A Retrospective Review of Patients Undergoing Total Capsulectomy and Removal of Breast Implants for Breast Implant Illness

Purpose:

Breast implant illness (BII) is a novel syndrome involving a constellation of symptoms, potentially driven by a reaction of the patient's immune system to her breast implants [1, 2]. This process is named by women who believe they have become ill from their implants and awareness of BII is fueled by the power of social media [3, 4]. BII symptoms are widespread and can affect all organ systems [5, 6]. Most studies regarding breast implants and systemic disease have occurred in nonsurgical fields with controversial conclusions [7-15]. We present a retrospective chart review of 244 patients who have presented to a single surgeon with BII symptoms and underwent bilateral implant removal and total capsulectomy.

Methods:

After IRB approval, we conducted a retrospective review of all women aged 18 and older who presented to the senior author with systemic symptoms that patients believed to be due to their breast implants and who went on to undergo total capsulectomy and removal of both implants.

Data obtained from the chart review included demographics, reason for initial placement of implants (reconstruction versus cosmetic), medical history, symptoms both before and after breast implant removal, and follow-up. Any labs obtained by the senior author or stated in the chart were reviewed. Preoperative physical exam findings, in addition to operative findings at the time of surgery were noted. Pathology results, and concomitant procedures at time of implant removal were reviewed as well. The first four post-operative visit notes were reviewed for each patient's level of satisfaction.

Results:

The study population consisted 244 patients collected over three years, from August 1, 2016 to June 30, 2019 who underwent bilateral implant removal and bilateral total capsulectomies with the senior author. The majority (93%) had implants placed for cosmetic purposes. The average patient age was 44, and average BMI was 24. Most patients (92%) were nonsmokers. On physical exam, most patients (54%) exhibited Baker II capsular contracture at initial presentation.

Most common symptoms mentioned at time of initial evaluation included generalized pain (159, 65%), fatigue (131, 54%), cognitive "fogginess" (102, 42%), migraines (90, 37%), headaches (85, 35%), anxiety (77, 32%), arthritis (66, 27%), vision changes (61, 25%), dyspnea (58, 24%), hair loss (52, 21%), weight gain (47, 19%), back pain (43, 18%), thyroid disease (43, 18%), rashes (42, 17%), generalized gastrointestinal issues (41, 17%), depression (39, 16%), and food intolerance (36, 15%). The number of complaints did not vary significantly between types of implants.

Simultaneous procedures at time of implant removal and total capsulectomy included mastopexy (52, 21%), scar revision (13, 5.3%), breast reconstruction (6, 2.5%), abdominoplasty (2, 0.8%), implant replacement (1, 0.4%). Four major complications occurred, which consisted of one pneumothorax that required hospital admission for observation and three breast hematomas that required evacuation in the OR. Minor complications consisted of several suture

infections in patients who received simultaneous mastopexies which were treated with antibiotics.

Seventy (40%) of the implants removed were Mentor saline. The remaining implants were Allergan silicone (36, 20%), Allergan saline (33, 19%), Mentor silicone (31, 18%), and finally Sientra silicone (6, 3%). Eighty-six percent of implants removed were smooth, while 14% were textured.

All capsules were sent to permanent pathology, and 106 (22%) of the capsules were found to have evidence of acute or chronic inflammation, which was defined as calcification or microcalcification, histiocytic reaction or an abundance of histiocytes/macrophages/giant cells, presence of sclerosis, lymphoid/lymphocytic infiltration, or the term "inflammation." One capsule did have atypical lymphocytic infiltration but was CD30 negative. The rate of inflammation between different makes and models of implants was significant. However, comparing all silicone implants to all saline implants, evidence of capsule inflammation was significantly more commonly in capsules associated with silicone implants at a rate of 29.67% compared to 16.31% in capsules associated with saline implants (p=0.0006).

The average number of follow-up visits was 3.9. Post-operative visit notes addressed specific symptoms in 44 patients, and of these, 41 (93%) reported a decrease in the number of symptoms after surgery. Overall, 85% of patients were pleased with the results of the surgery and were without complaints or expressed only minor complaints.

Conclusion:

Our study is limited as this was a retrospective chart review, thus we are limited on our ability to evaluate changes in specific symptoms which patients attributed to their breast implants. Furthermore, we have few objective markers of systemic disease to remark on the prevalence of elevated inflammatory markers in BII. However, evidence of inflammation was commonly noted in the excised capsules, and was significantly more common in silicone implants. This finding, in addition to the fact that most patients were pleased during the follow-up period suggests that there is an organic pathologic process involved in BII. We believe that total capsulectomy and implant removal in patients with suspected BII can be safely performed and with high patient satisfaction.

References:

1. Breast Implant Illness - Frequently Asked Questions/Talking Points. American Society for Aesthetic Plastic Surgery. https://www.surgery.org/sites/default/files/BreastImplantIllness_8-21-2019_FINAL.pdf
2. Magnusson MR, Cooter RD, Rakhorst H, et al. Breast Implant Illness: A Way Forward. *Plast Reconstr Surg*. 2019;143:74S-81S.
3. https://healingbreastimplantillness.com/
4. Tang S, Israel J, Afifi A. Breast Implant Illness: Symptoms, Patient Concerns, and the Power of Social Media. *Plast Reconstr Surg*. 2017 140(5):765e-766e.
5. Breast Implant Illness: How Can We Help? McGuire PA, Haws MJ, Nahai F. Aesthet Surg J. 2019. [Epub ahead of print]
6. Balk EM, Earley A, Avendano EA, Raman G. Long-Term Health Outcomes in Women With Silicone Gel Breast Implants: A Systematic Review. *Ann Intern Med*. 2016 2;164(3):164-75.

7. Watad A, Rosenberg V, Tiosano S, et al. Silicone breast implants and the risk of autoimmune/rheumatic disorders: a real-world analysis. *Int J Epidemiol*. 2018;47(6):1846-1854.
8. Lavanos G, Kouma D, Deveros A, et al. Still's-like Disease Induced by Breast Implants in a Middle-Aged Female Health Professional. *Eur J Case Rep Intern Med*. 2017;4(1):000513.
9. Coroneos CJ, Selber JC, Offodile AC et al. US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients. *Ann Surg*. 2019;269(1):30-36.
10. Swanson E. Analysis of US Food and Drug Administration Breast Implant Postapproval Studies Finding an Increased Risk of Diseases and Cancer: Why the Conclusions Are Unreliable. *Ann Plast Surg*. 2019;82(3):253-254.
11. Rohrich RJ, Kaplan J, Dayan E. Silicone Implant Illness: Science versus Myth? *Plast Reconstr Surg*. 2019;144(1):98-109.
12. McGuire PA, Haws MJ, Nahai F. Breast Implant Illness: How Can We Help? *Aesthet Surg J*. 2019 pii: sjz227. [Epub ahead of print]
13. Magnusson MR, Cooter RD, Rakhorst H, et al. Breast Implant Illness: A Way Forward. *Plast Reconstr Surg*. 2019;143:74S-81S.
14. U.S. Food and Drug Administration; Center for Devices and Radiological Health. FDA update on the safety of silicone gel-filled breast implants. Accessed on Sept 5, 2019 from: https://www.fda. gov/downloads/medicaldevices/productsandmedicalproce-dures/implantsandprosthetics/breastimplants/ucm260090.pdf.
15. Ashar BS. Assessing the Risks of Breast Implants and FDA's Vision for the National Breast Implant Registry. *Ann Surg*. 2019;269(1):37-38.